REMARKS

New claims 11-30 are all the claims pending in the application.

Claims 11-30 correspond to original claims 1-8, drawn to polypeptides, polynucleotides, vectors, and host cells. Applicants elected claims 1-8 (Group I) in response to the restriction requirement of February 20, 2001 in the parent application.

Specifically, new claims 11-30 recite polypeptides comprising the amino acid sequence shown in SEQ ID NO: 4 or 8, variants of said polypeptides, cDNA encoding said polypeptides or variants, related expression vectors and host cells, and methods for practicing the invention. Support for the claimed invention is found in the original claims and throughout the specification. Accordingly, no question of new matter arises and entry of this amendment is respectfully requested.

In the final Office Action in the parent application, mailed August 12, 2003, then pending claims 1-8 and 11-22 were rejected under 35 U.S.C. § 101 as lacking patentable utility. The Examiner asserted that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for reasons of record in the previous Office Actions (dated September 24, 2001 (at pages 3-6); June 19, 2002 (at pages 3-5); and January 17, 2003).

In response to Applicant's arguments in the Preliminary Amendment in the parent application, filed May 19, 2003, the Examiner stated that Applicants have provided convincing evidence that the claimed proteins are members of the TNF receptor superfamily. However, because of the diversity in the biological activity of these receptors, the Examiner concluded that membership in this class does not impute a specific, substantial, and credible utility to the polypeptides of the instant invention.

Furthermore, the Applicants argued in the Preliminary Amendment of May 19, 2003 that the protein of the present invention would be expected to have cell death promoting activity, based on its sequence homology to the TAJ protein of Eby et al. In response, the Examiner stated that even if the claimed protein can cause cell death and apoptosis, as taught in the Eby et al. reference, this utility is not supported by the specification as originally filed. The Examiner noted that although the instant application discusses the possible role of the proteins of the instant invention in apoptosis, the specification also describes a myriad of other activities which are based solely on the proteins belonging to the TNF family of receptors.

The Examiner further stated that the induction of cell death and apoptosis is not a patentable utility, because one of ordinary skill in the art would not know how to use the molecules of the instant invention without substantial further research to determine their role in apoptosis or involvement in any disease state. The Examiner explained that if the protein of the instant invention was found to be aberrantly expressed in a specific disease or disorder, this could possibly result in a patentable utility. However, because there is no nexus between the protein of the instant invention and any disease or disorder, the Examiner concluded that the Applicants have not disclosed a specific and substantial utility for the protein in treating or diagnosing disease.

In the final Office Action in the parent application, then pending claims 1-8 and 11-24 were also rejected under 35 U.S.C. § 112, first paragraph, as being non-enabled. The Examiner contended that since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the invention.

Applicants' Comments

Under MPEP 2107.02, "an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112; additional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility."

Applicants assert that the claimed invention is supported by a credible assertion of specific utility, namely the ability to induce cell death. For example, at page 17, lines 6-10, it is stated that the polypeptide of the present invention will show biological activities including cell death.

This activity is also supported in the disclosure of Eby et al., such as in the Abstract. As discussed in the Preliminary Amendment filed May 19, 2003, the TAJ protein of Eby et al. and the protein of the present invention are substantially the same. Thus, the protein of the present invention would be readily expected to have the same cell death inducing activity as established for the TAJ protein.

In addition, as discussed throughout Eby et al., the primary activity for the TAJ protein is predicted to be in embryonic development (*see, e.g.*, the Abstract; page 15336, column 2, lines 3-6; page 15340, column 2, lines 5-7). This activity is fully supported in the present specification, such as at page 18, lines 4-7, where cell proliferation and differentiation activities are discussed; at page 19, line 25 through page 20, line 1, where growth and proliferation of erythroid progenitor cells are discussed; page 20, line 6, where growth and proliferation of myeloid cells are discussed; page 20, line 10, where growth and proliferation of megakaryocytes are discussed; page 20, lines 15-16, where growth and proliferation of hematopoietic stem cells are discussed. Finally, as clearly stated at page 29, lines 13-21, the

protein of the present invention is involved in the early embryonic development of an organism.

Applicants further contend that induction of cell death and apoptosis is a patentable utility. Based on the disclosed activities of the present invention, supported by Eby et al., the skilled artisan would readily understand that a polypeptide involved in the induction of cell death could be used in a number of important manners. For example, a specific and substantial utility could be had in the preparation of an agent for treating or diagnosing diseases caused by uncontrolled cell death induced by the aberrant expression of the protein of the present invention. A discussion of some of the other specific utilities for the polypeptide of the present invention is provided at page 29, line 22, through page 30, line 8.

Furthermore, Applicants assert that the skilled artisan would clearly understand how to make and use the polypeptide of the present invention for the asserted utility without undue experimentation. The knowledge in the art and the expertise of an artisan working in the field of molecular biology is such that the skilled artisan would be able to use the claimed polypeptide for those uses discussed at page 29, line 22, through page 30, line 8, of the specification, without further specific instruction. One example would be in the induction of cell death in a population of cancer cells through the introduction into the population of an expression vector comprising the coding sequence of the polypeptide.

In conclusion, Applicants assert that the protein of the present invention would be expected to have cell death promoting activity, based on its sequence homology to the TAJ protein of Eby et al. Furthermore, as discussed above, a role for the TAJ protein in embryonic development has been disclosed in Eby et al., which is fully supported in the instant specification where numerous instances of a role for the protein in cellular

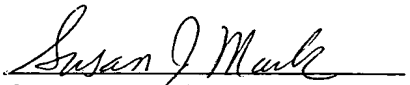
proliferation and differentiation are discussed. Finally, as also disclosed in the specification, a number of specific utilities for the protein are taught, and the skilled artisan would readily envision additional activities.

Thus, it is clear that a specific and substantial asserted utility has been disclosed for the polypeptide of the present invention, and that the experimental results in Eby et al. strongly support that utility. Given the specific and substantial asserted utility, and the knowledge of the skilled artisan, Applicants state that the present invention is adequately enabled.

In view of the above, the new claims are supported by patentable utility and are enabled, and allowance thereof is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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